

NIH POLICY MANUAL

3040-3 - INTRAMURAL CONTRACTS INVOLVING ANIMALS

Issuing Office: OD/OACU 496-5424

Release Date: 12/15/89

A. Purpose:

This chapter establishes responsibility for monitoring humane care and use of animals involved in research, research training, and biologic testing activities, herein referred to as activities, which are conducted under contract from elements of the NIH intramural research program.

B. Background:

In December 1985 the Health Research Extension Act, in effect, extended provisions of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) to the intramural research programs of the National Institutes of Health. Also, in 1985, the NIH intramural program, under mandate by the NIH Director, embarked on a major effort to attain accreditation of its animal care and use program by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). These events set in motion a review of practices relative to laboratory animal care and use in the intramural program.

Two results of the review were the revision of NIH Manual Chapter 3040-2, Animal Care and Use in the Intramural Program, and submission of the NIH Animal Welfare Assurance (Assurance) document to the Office for Protection from Research Risks (OPRR). The Manual Chapter establishes policies and procedures for animal care and use in intramural programs, and the NIH Assurance describes intramural NIH's plan to conform with the Guide for the Care and Use of Laboratory Animals (Guide) and PHS Policy. The above mentioned documents do not specifically address issues of conducting intramural research involving animals under contract. Furthermore, while the documents do not prescribe AAALAC accreditation, PHS policy provides accreditation as an institutional option for demonstrating conformance with standards of the Guide, and, an NIH plan to attain accreditation is now in effect. Accreditation of a contractor's animal care and use program greatly simplifies for the BID the process of assuring acceptable animal care practices at a contract site. It, however, is not a requirement.

This policy establishes the requirements for institutional (BID) oversight of contracts involving animals from elements of the intramural NIH research program, while

defining and differentiating the impact of attaining and maintaining AAALAC accreditation of either the intramural NIH animal care and use program, the contractor's programs, or both. Two points regarding AAALAC accreditation and the NIH Assurance are important: 1) AAALAC rules of accreditation state that when animals used at a contract site are owned by the parent institution, in this case NIH, either the contractor must have an AAALAC accredited program, or the contract facility and its animal care and use program become part of NIH's accreditation application and will, therefore, be site visited and will otherwise be subject to the NIH accreditation process. 2) Institutions receiving PHS funds for activities involving animals must either have their own Assurance on file and approved by OPRR or be included in the NIH Assurance. Under unusual circumstances, when it is necessary for an NIH contractor to be included in the NIH Assurance, the BID must assume responsibility for compliance of the contractor's animal care and use program with provisions of PHS Policy.

Most of the content of this policy is an assimilation, restatement, and re-emphasizing of previously established policies, regulations or guidelines. The major new requirements are involvement of the BID Animal Care and Use Committee in the prospective review of the statement of work for a contract involving animals, and maintaining an ongoing cognizance of activities involving animals at contract sites.

C. References:

1. PHS Acquisition Regulations 352.280-2, Care of Laboratory Animals, Federal Register, June 5, 1986, or as amended.
2. PHS Policy on Humane Care and Use of Laboratory Animals, Revised 1986. (PHS Policy)
3. NIH Manual Chapter 3040-2, Animal Care and Use in the Intramural Program.
4. Guide for the Care and Use of Laboratory Animals, DHHS, PHS, NIH Publication No. 85-23, Revised 1985. (Guide)

D. Definitions:

1. Animal: Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biologic testing, or for related purposes.
2. Assurance: The written Assurance of Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) prepared by PHS awardee institutions (including PHS agencies) which engage in activities involving animals. This assurance is submitted to and approved by the Office for Protection from Research Risks (OPRR), Office of Extramural Research (OER).
3. BID-Animal Care and Use Committee (BID-ACUC): The committee within each Institute or Division of NIH (BID), qualified through the experience and expertise of its members, and appointed by the Scientific Director to oversee

the institute's intramural animal program, facilities, and procedures. Each BID-ACUC serves as a subcommittee of the NIH-ACUC.

4. NIH Animal Care and Use Committee (NIH-ACUC): The intramural NIH Institutional Animal Care and Use Committee (IACUC) composed of the Chair of each BID-ACUC. The Deputy Director of Intramural Research shall appoint the Chair, Executive Secretary, and members as required by PHS Policy (IV.A.3).

E. Applicability:

This policy is applicable to all negotiated research and development (R&D) or R&D support contracts that provide services for scientific programs of NIH intramural laboratories. When a government-owned or contractor-owned, contractor-operated satellite facility, (defined in the NIH Assurance) has a separate assurance on file with the OPRR, the same responsibilities under this policy apply to all parties of the satellite facility and subcontractors of the satellite facility who receive PHS funds for activities involving animals.

F. Policy:

NIH intramural policy requires that all contracts for research, research training, experimentation, and biologic testing involving animals will be conducted in compliance with PHS Policy, the NIH Assurance, and local, state, or federal regulations.

G. Responsibilities:

1. The Deputy Director for Intramural Research, NIH, is responsible for assuring compliance by all BIDs having an intramural research program with the policy stated in section F.
2. The NIH-ACUC is responsible for:
 - a. Providing a forum for considering issues regarding activities involving animals under R&D contracts serving the intramural program.
 - b. Reviewing and approving, in consultation with OPRR, requests for waivers of a provision or provisions of this manual chapter (see section J).
3. The BID-ACUC is responsible for:
 - a. Consulting with project officers at the concept review phase or thereafter prior to solicitation, to provide advice and guidance, if necessary, in preparing the statement of work.
 - b. Reviewing, prior to solicitation and award, when changes in the statement of work are made between solicitation and award, those components of the statement of work related to the care and use of animals; and providing guidance, as necessary, to the project officer.
 - c. Reviewing copies of animal experimental protocols which have been

approved by the contractor's Institutional Animal Care and Use Committee (IACUC) in order to remain cognizant of animal research being funded by the BID's intramural program and to ensure consistency with applicable laws, acts, regulations, and guidelines.

d. Reviewing reports of contractor's activities submitted by the Project Officer or Contracting Officer in order to assure appropriate corrective action is taken when necessary.

e. Reviewing requests for waivers to this policy and, if in concurrence, submitting them to the NIH-ACUC for written approval (see section J).

4. The Contracting Officer is responsible for:

a. Ensuring review of the statement of work by the BID-ACUC prior to award.

b. Ensuring solicitations and contracts are in compliance with PHS Acquisition Regulations 352.280-2 and otherwise carrying out the responsibilities established in those regulations.

c. Reporting deviations from compliance with applicable animal welfare policies and regulations, or deficiencies of the contractor's animal care and use program to the BID-ACUC.

5. The Project Officer is responsible for:

a. Submitting the statement of work to BID-ACUC for review prior to award.

b. Ensuring animal experimental protocols, reviewed and approved by the contractor's IACUC and supported by the contract, are within the scope of the statement of work. A change to the statement of work, which involves the care or use of animals, must be reviewed by the BID-ACUC prior to implementation.

c. Receiving copies of approved animal experimental protocols supported by the contractor's IACUC within 20 working days of their approval and submitting them to the BID-ACUC. The Project Officer should consider making the approved animal experimental protocols deliverable under the terms of the contract to meet this time requirement.

d. Requesting and reviewing, as necessary to monitor compliance, copies of the contractor's USDA Reports of Inspection of Animal Facilities, Sites or Premises, VS Form 18.8; semiannual reports of IACUC evaluations required to be filed by PHS Policy; and other reports sent to OPRR in fulfillment of requirements of PHS Policy.

e. Reporting deviations from compliance with applicable animal welfare policies and regulations, or deficiencies of the contractor's animal care and use program to the Contracting Officer and the BID-ACUC.

H. AAALAC Accreditation Status and Actions Required:

1. Accredited Contractor: No further requirements. The Project Officer is encouraged to use the resources of the respective BID-ACUC to assist in the monitoring of contractor's performance for compliance with PHS Policy.

2. Non-Accredited Contractor - Animals owned by the Government: The Project Officer is responsible for coordinating activities, compiling information necessary for the AAALAC accreditation application, site visit, or annual AAALAC report, and responding to inquiries for additional material requested by AAALAC. The Project Officer is also responsible for assuring that corrective actions required by AAALAC are communicated to and accomplished by the contractor in a timely fashion.

3. Non-Accredited Contractor - Animals owned by the contractor: No further requirements. The Project Officer is encouraged to use the resources of the respective BID-ACUC to assist in the monitoring of contractor's compliance with PHS Policy.

I. Assurance Status:

1. Contractor with Assurance on file with OPRR:

a. No further requirements.

2. Contractor to be covered by NIH Assurance:

a. The BID assumes responsibility for assuring compliance of the contractor's animal care and use program with PHS Policy.

b. The BID-ACUC is responsible for reviewing the contractor's program and facilities when conducting semiannual evaluations, and performing other functions, as required by paragraph IV.B. of PHS Policy.

J. Waivers:

BIDs may request a waiver of a provision or provisions of this manual chapter by submitting a request from the BID-ACUC to the NIH-ACUC. Requests will be considered by the NIH-ACUC in consultation with OPRR, with written waivers granted to those providing sufficient justification.

K. Additional Information:

For further information on this manual chapter, contact the Office of Animal Care and Use, (OACU), Deputy Director for Intramural Research, OD, NIH, on 496-5424.

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